ERYTHROMYCIN - erythromycin base capsule, delayed release
Abott Laboratories

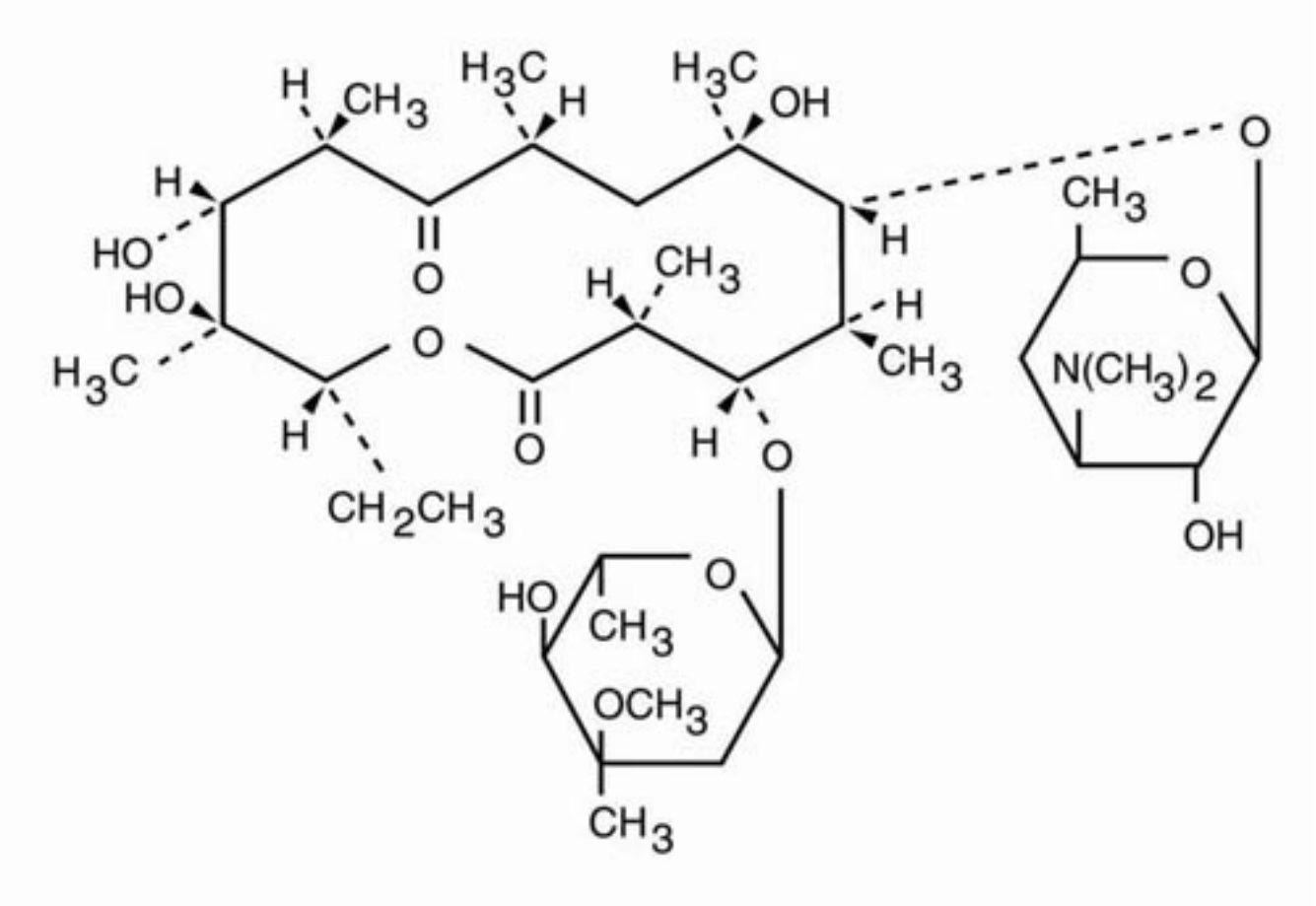
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Erythromycin Delayed-release Capsules and other antibacterial drugs, Erythromycin Delayed-release Capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION

Erythromycin Delayed-release Capsules contain enteric-coated pellets of erythromycin base for oral administration. Each Erythromycin Delayed-release Capsule contains 250 milligrams of erythromycin base.

Inactive Ingredients

Cellulosic polymers, citrate ester, D&C Red No. 30, D&C Yellow No. 10, magnesium stearate and povidone. The capsule shell contains FD&C Blue No. 1, FD&C Red No. 3, gelatin, and titanium dioxide.
Erythromycin is produced by a strain of *Saccharopolyspora erythaea* (formerly *Streptomyces erythraeus*) and belongs to the macrolide group of antibiotics. It is basic and readily forms salts with acids but it is the base which is microbiologically active.
Erythromycin base is (3R*, 4S*, 5S*, 6R*, 7R*, 9R*, 11R*, 12R*, 13S*, 14R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-L-*ribo*-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydroxy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione.



$C_{37}H_{67}NO_{13}$ MW 734

CLINICAL PHARMACOLOGY

Orally administered erythromycin base and its salts are readily absorbed in the microbiologically active form. Interindividual variations in the absorption of erythromycin are, however, observed, and some patients do not achieve acceptable serum levels. Erythromycin is largely bound to plasma proteins, and the freely dissociating bound fraction after administration of erythromycin base represents 90% of the total erythromycin absorbed. After absorption, erythromycin diffuses readily into most body fluids. In the absence of meningeal inflammation, low concentrations are normally achieved in the spinal fluid, but the passage of the drug across the blood-brain barrier increases in meningitis. The drug is excreted in human milk. The drug crosses the placental barrier, but plasma levels are low. Erythromycin is not removed by peritoneal dialysis or hemodialysis.

In the presence of normal hepatic function erythromycin is concentrated in the liver and is excreted in the bile; the effect of hepatic dysfunction on biliary excretion of erythromycin is not known. After oral administration, less than 5% of the administered dose can be recovered in the active form in the urine.
The enteric coating of pellets in Erythromycin Delayed-release Capsules protects the erythromycin base from inactivation by gastric acidity. Because of their small size and enteric coating, the pellets readily pass intact from the stomach to the small intestine and dissolve efficiently to allow absorption of erythromycin in a uniform manner. After administration of a single dose of a 250 mg Erythromycin Delayed-release Capsule, peak serum levels in the range of 1.13 to 1.68 mcg/mL are attained in approximately 3 hours and decline to 0.30-0.42 mcg/mL in 6 hours. Optimal conditions for stability in the presence of gastric secretion and for complete absorption are attained when erythromycin is taken on an empty stomach.

Microbiology
Erythromycin acts by inhibition of protein synthesis by binding 50 *S* ribosomal subunits of susceptible organisms. It does not affect nucleic acid synthesis. Antagonism has been demonstrated *in vitro* between erythromycin and clindamycin, lincomycin, and chloramphenicol.
Many strains of *Haemophilus influenzae* are resistant to erythromycin alone but are susceptible to erythromycin and sulfonamides used concomitantly.
Staphylococci resistant to erythromycin may emerge during a course of therapy.
Erythromycin has been shown to be active against most strains of the following microorganisms, both *in vitro*and in clinical infections as described in the **INDICATIONS AND USAGE** section.

Gram-positive organisms
Corynebacterium diphtheriae

Corynebacterium minutissimum

Listeria monocytogenes

Staphylococcus aureus (resistant organisms may emerge during treatment)

Streptococcus pneumoniae

Streptococcus pyogenes

Gram-negative organisms
Bordetella pertussis

Legionella pneumophila

Neisseria gonorrhoeae

Other microorganisms
Chlamydia trachomatis

Entamoeba histolytica

Mycoplasma pneumoniae

Treponema pallidum

Ureaplasma urealyticum

Susceptibility Tests

Dilution Techniques
Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MIC's). These MIC's provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MIC's should be determined using a standardized procedure.
Standardized procedures are based on a dilution method[1] (broth or agar) or equivalent with standardized inoculum concentrations and standardized concentrations of erythromycin powder. The MIC values should be interpreted according to the following criteria:

MIC (µg/mL)	Interpretation
≤ 0.5	Susceptible (S)

1-4	Intermediate (I)
≥ 8	Resistant (R)

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and, if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Standardized susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures. Standard erythromycin powder should provide the following MIC values:

Microorganism	**MIC (µg/mL)**
S. aureus ATCC 29213	0.12-0.5

Diffusion Techniques
Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure[2] requires the use of standardized inoculum concentrations. This procedure uses paper disks impregnated with 15-µg erythromycin to test the susceptibility of microorganisms to erythromycin.

Reports from the laboratory providing results of the standard single-disk susceptibility test with a 15-µg erythromycin disk should be interpreted according to the following criteria:

Zone Diameter (mm)	**Interpretation**
≥ 23	Susceptible (S)
14-22	Intermediate (I)
≤ 13	Resistant (R)

Interpretation should be as stated above for results using dilution techniques. Interpretation involves correlation of the diameter obtained in the disk test with the MIC for erythromycin.

As with standardized dilution techniques, diffusion methods require the use of laboratory control microorganisms that are used to control the technical aspects of the laboratory procedures. For the diffusion technique, the 15-µg erythromycin disk should provide the following zone diameters in these laboratory test quality control strains:

Microorganism	**Zone Diameter (mm)**
S. aureus ATCC 25923	22-30

INDICATIONS AND USAGE
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Erythromycin Delayed-release Capsules and other antibacterial drugs, Erythromycin Delayed-release Capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
Erythromycin is indicated in the treatment of infections caused by susceptible strains of the designated microorganisms in the diseases listed below:
Upper respiratory tract infections of mild to moderate degree caused by *Streptococcus pyogenes*, *Streptococcus pneumoniae*, or *Haemophilus influenzae* (when used concomitantly with adequate doses of sulfonamides, since many strains of *H. influenzae* are not susceptible to the erythromycin concentrations ordinarily achieved). (See appropriate sulfonamide labeling for prescribing information.)
Lower-respiratory tract infections of mild to moderate severity caused by *Streptococcus pneumoniae* or *Streptococcus pyogenes*.
Listeriosis caused by *Listeria monocytogenes*.
Pertussis (whooping cough) caused by *Bordetella pertussis*. Erythromycin is effective in eliminating the organism from the nasopharynx of infected individuals rendering them noninfectious. Some clinical studies suggest that erythromycin may be helpful in the prophylaxis of pertussis in exposed susceptible individuals.
Respiratory tract infections due to *Mycoplasma pneumoniae*.

Skin and skin structure infections of mild to moderate severity caused by *Streptococcus pyogenes* or *Staphylococcus aureus* (resistant staphylococci may emerge during treatment).
Diphtheria: Infections due to *Corynebacterium diphtheria*, as an adjunct to antitoxin, to prevent establishment of carriers and to eradicate the organism in carriers.
Erythrasma: In the treatment of infections due to *Corynebacterium minutissimum*.
Syphilis caused by *Treponema pallidum*: Erythromycin is an alternate choice of treatment for primary syphilis in penicillin-allergic patients. In treatment of primary syphilis, spinal fluid examinations should be done before treatment and as part of follow-up after therapy.
Intestinal amebiasis caused by *Entamoeba histolytica* (oral erythromycins only). Extraenteric amebiasis requires treatment with other agents.
Acute pelvic inflammatory disease caused by *Neisseria gonorrhoeae*: Erythromycin lactobionate for injection, USP followed by erythromycin base orally as an alternative drug in treatment of acute pelvic inflammatory disease caused by *N. gonorrhoeae* in female patients with a history of sensitivity to penicillin. Patients should have a serologic test for syphilis before receiving erythromycin as treatment of gonorrhea and a follow-up serologic test for syphilis after 3 months.
Erythromycins are indicated for the treatment of the following infections caused by *Chlamydia trachomatis*: conjunctivitis of the newborn, pneumonia of infancy, and urogenital infections during pregnancy. When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of uncomplicated urethral, endocervical, or rectal infections in adults due to *Chlamydia trachomatis*.
When tetracyclines are contraindicated or not tolerated, erythromycin is indicated for the treatment of nongonococcal urethritis caused by *Ureaplasma urealyticum*.
Legionnaires' Disease caused by *Legionella pneumophila*. Although no controlled clinical efficacy studies have been conducted, *in vitro* and limited preliminary clinical data suggest that erythromycin may be effective in treating Legionnaires' Disease.

Prophylaxis

Prevention of Initial Attacks of Rheumatic Fever
Penicillin is considered by the American Heart Association to be the drug of choice in the prevention of initial attacks of rheumatic fever (treatment of *Streptococcus pyogenes* infections of the upper respiratory tract, e.g., tonsillitis or pharyngitis). Erythromycin is indicated for the treatment of penicillin-allergic patients.[3] The therapeutic dose should be administered for 10 days.

Prevention of Recurrent Attacks of Rheumatic Fever
Penicillin or sulfonamides are considered by the American Heart Association to be the drugs of choice in the prevention of recurrent attacks of rheumatic fever. In patients who are allergic to penicillin and sulfonamides, oral erythromycin is recommended by the American Heart Association in the long-term prophylaxis of streptococcal pharyngitis (for the prevention of recurrent attacks of rheumatic fever).[3]

CONTRAINDICATIONS
Erythromycin is contraindicated in patients with known hypersensitivity to this antibiotic.
Erythromycin is contraindicated in patients taking terfenadine, astemizole, pimozide, or cisapride. (See **PRECAUTIONS- Drug Interactions**.)

WARNINGS
There have been reports of hepatic dysfunction, including increased liver enzymes, and hepatocellular and/or cholestatic hepatitis, with or without jaundice, occurring in patients receiving oral erythromycin products.
There have been reports suggesting that erythromycin does not reach the fetus in adequate concentration to prevent congenital syphilis. Infants born to women treated during pregnancy with oral erythromycin for early syphilis should be treated with an appropriate penicillin regimen.
Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with lovastatin. Therefore, patients receiving concomitant lovastatin and erythromycin should be carefully monitored for creatine kinase (CK) and serum transaminase levels. (See package insert for lovastatin.)
Pseudomembranous colitis has been reported with nearly all antibacterial agents, including erythromycin, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-associated colitis".
After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis.

PRECAUTIONS

Prescribing Erythromycin Delayed-release Capsules in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

General

Since erythromycin is principally excreted by the liver, caution should be exercised when erythromycin is administered to patients with impaired hepatic function. (See **CLINICAL PHARMACOLOGY**and **WARNINGS**.)

There have been reports that erythromycin may aggravate the weakness of patients with myasthenia gravis.

There have been reports of infantile hypertrophic pyloric stenosis (IHPS) occurring in infants following erythromycin therapy. In one cohort of 157 newborns who were given erythromycin for pertussis prophylaxis, seven neonates (5%) developed symptoms of non-bilious vomiting or irritability with feeding and were subsequently diagnosed as having IHPS requiring surgical pyloromyotomy. A possible dose-response effect was described with an absolute risk of IHPS of 5.1% for infants who took erythromycin for 8-14 days and 10% for infants who took erythromycin for 15-21 days.[4] Since erythromycin may be used in the treatment of conditions in infants which are associated with significant mortality or morbidity (such as pertussis or neonatal *Chlamydia trachomatis* infections), the benefit of erythromycin therapy needs to be weighed against the potential risk of developing IHPS. Parents should be informed to contact their physician if vomiting or irritability with feeding occurs.

Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi. If superinfection occurs, erythromycin should be discontinued and appropriate therapy instituted.

When indicated, incision and drainage or other surgical procedures should be performed in conjunction with antibiotic therapy.

Information for Patients

Patients should be counseled that antibacterial drugs including Erythromycin Delayed-release Capsules should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Erythromycin Delayed-release Capsules is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Erythromycin Delayed-release Capsules or other antibacterial drugs in the future.

Drug Interactions

Erythromycin use in patients who are receiving high doses of theophylline may be associated with an increase in serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.

Concomitant administration of erythromycin and digoxin has been reported to result in elevated digoxin serum levels.

There have been reports of increased anticoagulant effects when erythromycin and oral anticoagulants were used concomitantly. Increased anticoagulation effects due to interactions of erythromycin with various oral anticoagulants may be more pronounced in the elderly.

Erythromycin is a substrate and inhibitor of the 3A isoform subfamily of the cytochrome P450 enzyme system (CYP3A). Coadministration of erythromycin and a drug primarily metabolized by CYP3A may be associated with elevations in drug concentrations that could increase or prolong both the therapeutic and adverse effects of the concomitant drug. Dosage adjustments may be considered, and when possible, serum concentrations of drugs primarily metabolized by CYP3A should be monitored closely in patients concurrently receiving erythromycin.

The following are examples of some clinically significant CYP3A based drug interactions. Interactions with other drugs metabolized by the CYP3A isoform are also possible. The following CYP3A based drug interactions have been observed with erythromycin products in post-marketing experience:

Ergotamine/dihydroergotamine

Concurrent use of erythromycin and ergotamine or dihydroergotamine has been associated in some patients with acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.

Triazolobenzodiazepines (such as triazolam and alprazolam) and related benzodiazepines

Erythromycin has been reported to decrease the clearance of triazolam and midazolam, and thus, may increase the pharmacologic effect of these benzodiazepines.

HMG-CoA Reductase Inhibitors

Erythromycin has been reported to increase concentrations of HMG-CoA reductase inhibitors (e.g., lovastatin and simvastatin). Rare reports of rhabdomyolysis have been reported in patients taking these drugs concomitantly.

Sildenafil (Viagra)

Erythromycin has been reported to increase the systemic exposure (AUC) of sildenafil. Reduction of sildenafil dosage should be considered. (See Viagra package insert.)

There have been spontaneous or published reports of CYP3A based interactions of erythromycin with cyclosporine, carbamazepine, tacrolimus, alfentanil, disopyramide, rifabutin, quinidine, methylprednisolone, cilostazol, vinblastine, and bromocriptine.

Concomitant administration of erythromycin with cisapride, pimozide, astemizole, or terfenadine is contraindicated. (See **CONTRAINDICATIONS**.)

In addition, there have been reports of interactions of erythromycin with drugs not thought to be metabolized by CYP3A, including hexobarbital, phenytoin, and valproate.

Erythromycin has been reported to significantly alter the metabolism of the nonsedating antihistamines terfenadine and astemizole when taken concomitantly. Rare cases of serious cardiovascular adverse events, including electrocardiographic QT/QT_c interval prolongation, cardiac arrest, torsades de pointes, and other ventricular arrhythmias have been observed. (See **CONTRAINDICATIONS**.) In addition, deaths have been reported rarely with concomitant administration of terfenadine and erythromycin.

There have been post-marketing reports of drug interactions when erythromycin was coadministered with cisapride, resulting in QT prolongation, cardiac arrhythmias, ventricular tachycardia, ventricular fibrillation, and torsades de pointes most likely due to the inhibition of hepatic metabolism of cisapride by erythromycin. Fatalities have been reported. (See **CONTRAINDICATIONS**.)

Drug/Laboratory Test Interactions
Erythromycin interferes with the fluorometric determination of urinary catecholamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term (2-year) oral studies conducted in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity. Mutagenicity studies have not been conducted. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25 percent of diet.

Pregnancy

Teratogenic Effects

Pregnancy Category B
There is no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25 percent of diet) prior to and during mating, during gestation,and through weaning of two successive litters. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery
The effect of erythromycin on labor and delivery is unknown.

Nursing Mothers
Erythromycin is excreted in human milk. Caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use
See **INDICATIONS AND USAGE** and **DOSAGE AND ADMINISTRATION** sections.

ADVERSE REACTIONS
The most frequent side effects of oral erythromycin preparations are gastrointestinal and are dose-related. They include nausea, vomiting, abdominal pain, diarrhea and anorexia. Symptoms of hepatitis, hepatic dysfunction and/or abnormal liver function test results may occur. Onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment. (See **WARNINGS**.)
Erythromycin has been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes.
Allergic reactions ranging from urticaria to anaphylaxis have occurred. Skin reactions ranging from mild eruptions to erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported rarely.
There have been rare reports of pancreatitis and convulsions.
There have been isolated reports of reversible hearing loss occurring chiefly in patients with renal insufficiency and in patients receiving high doses of erythromycin.

OVERDOSAGE
In case of overdosage, erythromycin should be discontinued. Overdosage should be handled with the prompt elimination of unabsorbed drug and all other appropriate measures.

Erythromycin is not removed by peritoneal dialysis or hemodialysis.

DOSAGE AND ADMINISTRATION

Erythromycin is well absorbed and may be given without regard to meals. Optimum blood levels are obtained in a fasting state (administration at least one half hour and preferably two hours before or after a meal); however, blood levels obtained upon administration of enteric-coated erythromycin products in the presence of food are still above minimal inhibitory concentrations (MICs) of most organisms for which erythromycin is indicated.

Adults

The usual dose is 250 mg every 6 hours taken one hour before meals. If twice-a-day dosage is desired, the recommended dose is 500 mg every 12 hours. Dosage may be increased up to 4 grams per day, according to the severity of infection. Twice-a-day dosing is not recommended when doses larger than 1 gram daily are administered.

Children

Age, weight, and severity of the infection are important factors in determining the proper dosage. The usual dosage is 30 to 50 mg/kg/day, in divided doses. For the treatment of more severe infections, this dose may be doubled.

Streptococcal Infections

A therapeutic dosage of oral erythromycin should be administered for at least 10 days. For continuous prophylaxis against recurrences of streptococcal infections in persons with a history of rheumatic heart disease, the dose is 250 mg twice a day.

Primary Syphilis

30 to 40 grams given in divided doses over a period of 10 - 15 days.

Intestinal Amebiasis

250 mg four times daily for 10 to 14 days for adults; 30 to 50 mg/kg/day in divided doses for 10 to 14 days for children.

Legionnaires' Disease

Although optimal doses have not been established, doses utilized in reported clinical data were those recommended above (1 to 4 grams daily in divided doses).

Urogenital Infections During Pregnancy Due to *Chlamydia trachomatis*

Although the optimal dose and duration of therapy have not been established, the suggested treatment is erythromycin 500 mg, by mouth, 4 times a day on an empty stomach for at least 7 days. For women who cannot tolerate this regimen, a decreased dose of 250 mg, by mouth, 4 times a day should be used for at least 14 days.

For adults with uncomplicated urethral, endocervical, or rectal infections caused by *Chlamydia trachomatis* in whom tetracyclines are contraindicated or not tolerated

500 mg, by mouth, 4 times a day for at least 7 days.

Pertussis

Although optimum dosage and duration of therapy have not been established, doses of erythromycin utilized in reported clinical studies were 40 - 50 mg/kg/day, given in divided doses for 5 to 14 days.

Nongonococcal Urethritis Due to *Ureaplasma urealyticum*

When tetracycline is contraindicated or not tolerated: 500 mg of erythromycin, orally, four times daily for at least 7 days.

Acute Pelvic Inflammatory Disease Due to *N. gonorrhoeae*

500 mg IV of erythromycin lactobionate for injection, USP every 6 hours for 3 days followed by 250 mg of erythromycin, orally every 6 hours for 7 days.

HOW SUPPLIED

Erythromycin Delayed-release Capsules, USP, are clear and opaque maroon capsules bearing the corporate **Abbott“A” logo** and Abbo-Code ER with pink and yellow particles containing 250 mg of erythromycin supplied in bottles of 100 (**NDC** 0074-6301-13) and 500 (**NDC** 0074-6301-53).

Recommended Storage

Store below 86°F (30°C). Protect from moisture and excessive heat.

REFERENCES

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2. National Committee for Clinical Laboratory Standards, *Performance Standards for Antimicrobial Disk Susceptibility Tests*, Fifth Edition. Approved Standard NCCLS Document M2-A5, Vol. 13, No. 24 NCCLS, Villanova , PA, December 1993.

3. Committee on Rheumatic Fever, Endocarditis, and Kawasaki Disease of the Council on Cardiovascular Disease in the Young, the American Heart Association: Prevention of Rheumatic Fever. Special Report *Circulation*. 78(4):1082-1086, October 1988.

4. Honein, M.A., et. al.: Infantile hypertrophic pyloric stenosis after pertussis prophylaxis with erythromycin: a case review and cohort study. The Lancet 1999; 354 (9196): 2101-5.

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